

### Remarks

Claims 12-16, 30-41 and 50-66 are pending in this application. No claim amendments are made in this paper. Applicant respectfully submits that all of the pending claims are allowable for at least the following reasons.

#### The Rejection Under 35 U.S.C. § 112, ¶1 Should Be Withdrawn

On pages 2-3 of the Office Action, claims 12-16 and 30-41, and 50-66 are rejected for alleged lack of enablement in the specification. In particular, it is alleged that the claims, while being enabling for treating allergic rhinitis, does not enable those of ordinary skill in the art to use the claimed invention for the prevention of allergic rhinitis. Applicant respectfully traverses this rejection.

The test of enablement is whether one reasonably skilled in the art could make or use the invention from the disclosures in the patent coupled with information known in the art without undue experimentation. *U.S. v. Telecommunications, Inc.*, 857 F.2d 778, 785 (Fed. Cir. 1988). The examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *Manual of Patent Examining Procedure* (“MPEP”) § 2164.04 (citing *In re Wright*, 999 F.2d 1557, 1562 (Fed. Cir. 1993)). Accordingly:

A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented *must be taken as being in compliance with the enablement requirement ... unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support*

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It is incumbent upon the Patent Office, whenever a rejection on this basis is made, to *explain why it doubts the truth or accuracy of any statement in a supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement.*

*Id.* (emphases added).

Applicant respectfully submits that the pending claims are enabled because the specification “contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented.” *Id.* For example, the specification teaches that

allergic rhinitis can be prevented by administering to a patient a therapeutically effective amount of norastemizole, or a pharmaceutically acceptable salt thereof, and a therapeutically effective amount of a leukotriene inhibitor. The specification, page 3, lines 7-12. Methods of preparing norastemizole are described on page 14 of the specification. Detailed description of leukotriene inhibitors, many of which are either commercially available, or can be synthesized using conventional methods, is on pages 9-10 of the specification. Dosages and routes of administration are described, for example, on pages 10-12 of the specification. All that is required for those of ordinary skill in the art to practice the claimed invention is to administer the specified amount of the specified compounds using the specified routes of administration. Therefore, it is clear that a sufficient guidance is provided in the specification so as to allow those of ordinary skill in the art to make and use the claimed invention.

Despite this fact, the Examiner, based on the analysis of factors set forth in *In re Wands*, 858 F.2d 731, 737 (Fed. Cir. 1988), alleges that the pending claims are not enabled. However, Applicant respectfully submits that the Examiner has not provided any relevant factual basis for her analysis of *Wands* factors. For example, while it is alleged that the relative skill in the art is “high,” and the unpredictability of preventing an allergic condition is very “high,” no factual support for these allegations is provided in the Office Action.<sup>1</sup>

Applicant also disagrees with the allegation that the specification fails to provide sufficient guidance for those of ordinary skill in the art because “a disclosure should contain representative examples which provide reasonable assurance to one skilled in the art that the methods will fall within the scope of a claim and will possess the alleged activity.” Office Action, page 3, citing *In re Riat*, 327 F.2d 685 (C.C.P.A. 1964) and *In re Barr*, 444 F.2d 588 (C.C.P.A. 1971). However, none of these cases stand for the proposition that “reasonable assurance” the methods “will possess the alleged activity” should be provided. In fact, these cases do not even concern enablement issues.

The standard applied by the Examiner is legally incorrect: there is no requirement that those of ordinary skill in the art must be able to ascertain the claimed invention from the specification for the specification to be enabling. Instead, the standard is whether those of ordinary skill in the art would be able to make and use the claimed

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<sup>1</sup> In fact, Applicant submits that these two allegations cut against each other.

invention. *See Telelectronics, Inc.*, 857 F.2d at 785. Thus, Applicant respectfully submits that an additional reason exists for withdrawing the rejection under 35 U.S.C. § 112.

Moreover, Applicant respectfully submits that no undue experimentation is necessary, contrary to what is alleged in the Office Action. Some factors that may --but need not<sup>2</sup>-- be considered in determining whether experimentation is undue include the quantity of experimentation necessary and the amount of direction or guidance provided. *In re Wands*, 858 F.2d at 737. In *Wands*, the Court of Appeals for the Federal Circuit held that claims directed to immunoassay methods were enabled even though in order to practice the claimed invention, one would have to screen "hybridomas to determine which ones secrete antibody with desired characteristics." This was because "[p]ractitioners of this art are prepared to screen negative hybridomas in order to find one that makes the desired antibody." *Id.* at 740.

As in *Wands*, the Examiner here is objecting to what is basically a screening step. Yet here, the screening is not nearly as complex, as the claimed invention is directed to the use of specific, readily obtainable compounds, for which routes of administration and amounts are set forth in the specification. Moreover, the determination by a physician as to whether the combination of norastemizole and a leukotriene inhibitor is effective in preventing allergic rhinitis in a given patient is a type of determination that is always made by physicians for every pharmaceutical. Indeed, the determination is a routine one that every physician is prepared to make, and which requires little or no effort. Therefore, Applicant respectfully submits that one reasonably skilled in the art could make or use the invention as claimed without undue experimentation.

In sum, Applicant respectfully submits that: (1) the specification provides sufficient information and guidance to those of ordinary skill in the art to make and use the claimed invention; and (2) to the extent any experimentation is necessary, such experimentation is not undue. Therefore, Applicant respectfully requests that the rejection of the claims under 35 U.S.C. § 112, ¶ 1, be withdrawn.

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<sup>2</sup> *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1230 (Fed. Cir. 1991), *cert. denied*, 502 U.S. 856 (1991) ("it is not necessary that a court review all the *Wands* factors to find a disclosure enabling. They are illustrative, not mandatory.").

The Rejection Under 35 U.S.C. § 103 Should Be Withdrawn

On pages 4-5 of the Office Action, claims 12-16, 30-41 and 50-66 are rejected as allegedly obvious over U.S. Patent No. 5,120,758 to Satoh (“Satoh”) in view of U.S. Patent No. 5,990,147 to Aslanian (“Aslanian”). In particular, it is alleged that because Satoh discloses that certain lipoxygenase inhibitors can be combined with an antihistamine, including astemizole, and Aslanian discloses that a certain H<sub>3</sub> receptor antagonist can be combined with an H<sub>1</sub> receptor antagonist, including astemizole and norastemizole, the pending claims are obvious. Applicant respectfully traverses this rejection.

The Patent Office bears the burden of establishing a *prima facie* case of obviousness under 35 U.S.C. § 103. *In re Deuel*, 51 F.3d 1552, 1557 (Fed. Cir. 1995); *In re Rijckaert*, 9 F.3d 1531, 1532 (Fed. Cir. 1993). To establish a *prima facie* case of obviousness, the Patent Office must first show that the prior art suggested to those of ordinary skill in the art that they should make the claimed composition or device or carry out the claimed process. Second, it must show that the prior art would have provided one of ordinary skill in the art with a reasonable expectation of success. Both the suggestion and the reasonable expectation of success must be adequately founded in the prior art and not in an applicant’s disclosure. Hindsight cannot be used to reject a claim as obvious. *In re Sernaker*, 702 F.2d 989, 994 (Fed. Cir. 1983). Third, the Patent Office must show that the prior art teaches or suggests all the claim limitations. Manual of Patent Examining Procedure § 2143; *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991). These criteria must be satisfied with factual and objective evidence found in the prior art: an examiner’s conclusory statements cannot form a basis for a *prima facie* case of obviousness. *In re Sang-Su Lee*, 277 F.3d 1338, 1343-4 (Fed. Cir. 2002).

As Applicant previously submitted, Satoh cannot render the pending claims obvious because Satoh does not place any limits as to the type of second active agent that can be combined with the lipoxygenase inhibitors it discloses. The Examiner finds this unpersuasive, because the arguments “are not commensurate with the scope of the claims.” Office Action, page 6. Specifically, the Examiner alleges that the pending claims are obvious over Satoh because: 1) the pending claims require a leukotriene inhibitor, and Satoh discloses lipoxygenase inhibitors; and 2) Satoh clearly states the combination of a lipoxygenase inhibitor and a second active agent such as antihistamines. *Id.* Applicant respectfully submits that not only does this conclusion beg the question, but it is also legally incorrect.

As well-settled, a disclosure of a genus does not necessarily render obvious a claimed species encompassed by that genus. *See, e.g., In re Jones*, 958 F.2d 347, 350 (Fed. Cir. 1992). Moreover, the prior art must suggest to one of ordinary skill in the art the desirability of the claimed combination. *See C.R. Bard Inc. v. M3 Systems, Inc.*, 157 F.3d 1340, 1352 (Fed. Cir. 1998), citing *Fromson v. Advance Offset Plate, Inc.*, 755 F.2d 1549, 1556 (Fed. Cir. 1985). Nowhere does Satoh suggest that combining an antihistamine, much less astemizole, would be more desirable than combining other numerous second agents it discloses. Thus, it is clear that choosing astemizole from among the broad range of therapeutic agents disclosed in Satoh, not to mention combining that selection with a reference that discloses the use of norastemizole, requires the use of impermissible hindsight.

Aslanian does not cure this deficiency. Aslanian discloses a genus of compounds that are reportedly effective as H<sub>3</sub> receptor antagonists. Aslanian, col. 2, lines 1-45 and 63-66. Aslanian also discloses that certain H<sub>3</sub> receptor antagonists can be combined with a laundry list of H<sub>1</sub> receptor antagonists, which happens to include norastemizole. *Id.*, col. 4, lines 41-67. Aslanian does not even disclose a leukotriene inhibitor. Thus, it is clear that Aslanian does not provide any motivation to combine it with Satoh, because, even assuming that it somehow suggest the desirability of norastemizole,<sup>3</sup> it does not teach that norastemizole can be combined with a leukotriene inhibitor.

Despite these well-settled legal principles, it is stated in the Office Action that to the extent that the cited references are used for a rejection under § 103, “certain amount of picking and choosing amongst the disclosed species is permitted.” Office Action, page 7. Not only does the Office Action provide no support for this statement, this statement is flatly contrary to the legal principles. The cases are clear on the point that “picking and choosing” is an impermissible approach for the assessment of obviousness. *See, e.g., Symbol Technologies, Inc. v. Opticon, Inc.*, 935 F.2d 1569, 1576 (Fed. Cir. 1991) (“We do not ‘pick and choose among the individual elements of assorted prior art references to create the claimed invention,’ but rather, we look for ‘some teaching or suggestion in the references to support their use in the particular claimed combination.’”). Therefore, Applicant respectfully submits that the rejection of the

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<sup>3</sup> Applicant submits it does not teach the desirability of norastemizole, for the same reasons discussed with respect to Satoh.

pending claims, to the extent that it is based on an incorrect legal principle, should be withdrawn.

In sum, Applicant submits that the pending claims are not obvious over Satoh and Aslanian at least because: 1) neither reference provides any suggestion to single out astemizole or norastemizole from the laundry list of second agents that they disclose; 2) neither reference provides any motivation to combine the two; and 3) the Examiner impermissibly ‘picks and chooses’ the elements of the claimed invention despite the fact that there is no suggestion or motivation in the cited references. Therefore, Applicant respectfully requests that the rejection under 35 U.S.C. § 103 be withdrawn.

### **Conclusion**

Applicant respectfully submits that all claims currently pending in this application are allowable, and requests that their rejections be withdrawn.

No fee is believed due for this submission. Should any additional fees be required for this submission or to avoid abandonment of the application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

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